VACCINES FOR HIV

SUMMARY

The development of an effective HIV vaccine has been an ongoing area of research. The high variability in HIV-1 virus strains has represented a major challenge in successful development. Ideally, an effective candidate vaccine would provide protection against the majority of clades of HIV. Two major hurdles to overcome are immunodominance and sequence diversity. This vaccine utilizes a strategy for overcoming these two issues by identifying the conserved regions of the virus and exploiting them for use in a targeted therapy. NCI seeks licensees and/or research collaborators to commercialize this technology, which has been validated in macaque models.

REFERENCE NUMBER

E-087-2015

PRODUCT TYPE

- Vaccines

KEYWORDS

- HIV vaccine, immunogenic conserved elements, Gag, Env

COLLABORATION OPPORTUNITY

This invention is available for licensing and co-development.

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DESCRIPTION OF TECHNOLOGY

The development of an effective HIV vaccine has been an ongoing area of research. The high variability in HIV-1 virus strains has represented a major challenge in successful development. Ideally, an effective candidate vaccine would provide protection against the majority of clades of HIV. Two major hurdles to overcome are immunodominance and sequence diversity. This vaccine utilizes a strategy for overcoming these two issues by identifying the conserved regions of the virus and exploiting them for use in a targeted therapy.

Researchers at the National Cancer Institute's Vaccine Branch used conserved elements (CEs) of the polypeptides Gag and Env as immunogenic compositions to induce an immune response to HIV-1

envelope polypeptides and Gag polypeptides. This invention is based, in part, on the discovery that the administration of one or more polypeptides comprising CEs, separated by linkers and collinearly arranged, of HIV Env or Gag CE proteins, can provide a robust immune response compared to administration of a full-length Env or Gag protein. The Env-CE DNA vaccines were tested in a rhesus macaque model and were able to induce a cellular and humoral immune response in this model whereas vaccination with the full length DNA did not produce the same effect.

A robust increase in immunity was observed when rhesus macaques were subjected to a prime-boost protocol. First, rhesus macaques were primed with Env-CE DNA and boosted with full length Env resulting in an observed increase in both the cellular and humoral responses. A further increase in immune response was observed from priming with CE and boosting with a combination of CE and full length DNA resulting in a significantly improved breadth of immune responses. These improved protocols may help solve the immunodominance problem observed in current protocols. This is considered a major obstacle for HIV vaccine development. The CE vaccines described by this invention have potential for use as prophylactic and therapeutic HIV vaccines.

POTENTIAL COMMERCIAL APPLICATIONS

- HIV vaccines

COMPETITIVE ADVANTAGES

- Addresses two key hurdles faced by current HIV vaccines: sequence diversity of HIV and immunodominance.
- Induces cross-clade specific immune response.
- The prime-boost immunization regimen is not limited to HIV, but can be employed to improve the induction of immune responses to any subdominant epitopes (cellular or humoral) to increase breadth, magnitude and quality of the immune response.

INVENTOR(S)

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DEVELOPMENT STAGE

- Pre-clinical (in vivo)

PUBLICATIONS

- Kulkarni, V. et al. PLoS One 9:e86254. 2014.
- Kulkarni, V. et al. PLos One 9(10):e111085. 2014

PATENT STATUS

- **U.S. Provisional:** US Provisional Patent App. # 62/161,123, filed on May 13, 2015
- **U.S. Provisional:** US Provisional Patent App.#62/241,599, filed on October 14, 2015

- **Foreign Filed:** International Patent App.# PCT/US2016/032317; filed on May 13, 2016

RELATED TECHNOLOGIES

- E-132-2012

THERAPEUTIC AREA

- Infectious Diseases